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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,646	03/29/2004	Anan Chuntharapai	11669.144USC1	5699

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	PAPER NUMBER
1649	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/813,646	CHUNTHARAPAI ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *47* is/are allowed.

6)☒ Claim(s) *11-46,48 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *082304*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 1/16/2007, have been entered in full. Applicant's timely response, 1/16/2007, to the restriction requirement of 11/15/2006 is acknowledge. Claims 1-10 have been canceled and new claims 11-49 are pending. All currently pending claims and now under examination.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 48 and 49 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10 and 5, respectively, of prior U.S. Patent No. 6713609. This is a double patenting rejection. Instant claim 48 and patented claim 10 are both directed to the same product i.e. a monoclonal antibody designated 2E1 produced by a hybridoma having deposit no. ATCC HB12133; thus the claims are of identical scope. Instant claim 49 and patented claim 5 are directed to the same product i.e. a monoclonal antibody designated 4A7 produced by a hybridoma having deposit no. ATCC HB12132; thus the claims are of identical scope.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-25, 27-32, 39-45, 48 and 49 are rejected on the ground of nonstatutory double patenting over claims 1-18 of U. S. Patent No. 6713609 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: anti-IFNAR1 monoclonal antibodies, that block/inhibit the antiviral activitiy of a first type I interferon but does not block that of a second type I interferon (IFN-beta), wherein the antibodies either bind to amino acids 244-249 and/or 291-298 of SEQ ID NO: 22 (e.g. antibody 2E1), or do not (e.g. antibody 4A7); hybridomas producing the antibodies, humanized and synthetic versions of the antibodies [0039], and methods of detecting IFNAR1 with the

antibodies [0050] are fully disclosed in the patent and not patentably distinct from the antibodies themselves.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-26 and dependent claims 27, 28 and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-23 require the antibodies to have a certain "EC_{50}" value. Although the concept of EC_{50} is commonly understood in the art of pharmacology, the specification defines it in a relative way against a standard that is not defined. At [0131] (patent publication), the specification indicates that this standard is a preselected number of units of an IFN-alpha, yet the specification does not set forth exactly how the number is preselected; thus the artisan could not be reasonably sure that he or she were in possession of what Applicant considers the claimed invention to be.

Claims 24-26 the claims recite the phrase, (e.g. claim 24) "ATCC deposit No. HB12133" yet this phrase is not grammatically connected in any meaningful way to the rest of the claim, e.g. does it refer to the claimed antibody or to a reference antibody? Thus the metes and bounds of the claims can not be determined.

Claim 26 recites "antibody 5H8", however there appears to be no such antibody taught in the specification. This appears to be a typographical error, and should read "5A8". Appropriate correction or clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth above, it is assumed that the claims relate to monoclonal antibody 5A8. Although the specification teaches that this antibody binds IFNAR1, and would thus be useful in the methods of claims 39-42, the claims depend from claim 11 which states that the antibody must have the ability to inhibit the antiviral activity of a type I interferon. The specification states that the 5A8 antibody does not inhibit the activity of any of the tested interferons, see table III. Thus, the artisan would not know how to make the claimed antibody function as required by the claims. It is noted that claim 46 would be allowable if written in independent form.

Claims 27, 28 and 33-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies and methods as the claims relate to an antibody

of parent claims 11, 24 and 25, does not reasonably provide enablement for antibodies and methods as the claims relate to an antibody from parent claim 26. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. As discussed above regarding claim 26, the 5A8 antibody does not appear to have the property of inhibiting the activity of any of the tested interferons, such being a required property of claim 27 and 28 (because they ultimately depend on claim 11) and for the additional reason that the treatment claims 33-38 require this property to function, see [0047]. Thus, the artisan would not know how to make the claimed antibody function as required by the claims.

Allowable Subject Matter

Claim 47 is allowed.

Additional References:

The following references are not being relied upon as the basis for any rejection in this Office action but are considered relevant to the use of anti-IFNAR1 antibodies in the treatment of immune-mediated disorders:

Pogue-SL et al., J. Interferon & Cytokine Res. 24(131-139)2004

Magnusson-M et al., Arthritis & Rheumatism 54(1)148-157, 2006

Borg, F.A.Y et al., Current Opinion in Rheumatology 19(61-66)2007

Dall'era-MC et al., ABSTRACT, Ann Rhem Dis 64(12)p 1692, 2005

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867. Official papers filed by fax should be directed to **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

March 28, 2007

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER